REMARKS

Claims 26 – 44 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lokkesmoe *et al.*, US Patent 5,674,538 and Huber, US Patent 4,013,581. As Applicant points out in the specification, to understand the value of the claimed invention, it is imperative to distinguish between sterilization and disinfection, the prior destroying essentially all microbial life while the latter destroys most, but not essentially all, microbial life. *See* Specification (p. 4, lines 11-14).

Lokkesmoe discloses the use of diperacids for disinfection, not sterilization. Lokkesmoe discloses and teaches an "antimicrobial agent" at concentration of between about 5 to about 100 ppm. *See*, for example, Lokkesmoe (claim 1 and Tables 2 and 3 at column 10). Applicant claims the use of dipercarboxylic acids at concentrations of at least 0.1 wt. %.

This difference is significant because Lokkesmoe teaches only using diperacids as a disinfectant and Applicant claims concentrations suitable for sterilization. It is not obvious to increase the concentration because it was generally unknown by those having ordinary skill in the art, that dipercarboxylic acids could be dissolved in water at a high enough concentration to form a sterilization solution. *See*, for example,
Specification at page 2, citing Eggensperger, *et al.*, U.S. Patent 4,129,517.

Furthermore, Lokkesmoe teaches using dipercarboxylic acids as a liquid, in the presence of equilibrium amounts of hydrogen peroxide, not a solid that is then dissolved in water to form the solution. Applicant claims the solid, which may be dissolved in water without the presence of the equilibrium amount of hydrogen peroxide that exists when dipercarboxylic acid is formed as a liquid for use as a disinfectant.

Huber teaches a bleach tablet formed for the purpose of providing a compound that may be added to laundry being washed to bleach the laundry. The concentration of the bleach is from about 5 to about 200 ppm. *See* Huber (column 5, lines 10-11). Huber does not teach nor suggest that the dipercarboxylic acid may be dissolved in water to form at least a 0.1 wt. % dipercarboxylic acid concentration as claimed by Applicant.

Applicant agrees with the Examiner's statement that the same composition may not be distinguished by serving two different purposes. However, the rule that no product patent may issue for discovery of a new use for an old product is tempered by the doctrine of slight changes. As stated in *Caterpillar Tractor Co. v. Berco, S.P.A.*, 215 USPQ 948, 959 (D. Wyo. 1982), *aff'd on other grounds*, 714 F.2d 1110 (Fed. Cir. 1983), "even small differences in art may establish patentability where the difference is distinctive, has great utility, and is not obvious." *Id.*

In *In re Wiggins*, 397 F.2d 356, 359 (CCPA 1966), the Court found that adding a known, old composition to a solvent to make a pharmaceutical preparation containing the old composition was a sufficient slight change to make the new compound, comprising the old compound and a solvent in a given concentration, patentable. A copy of this case is attached for the convenience of the Examiner.

Therefore, based on the analysis of *Caterpillar Tractor, supra*, Applicant must show that the claimed compound is distinctive, has great utility and is not obvious.

Applicant believes that the use of solid dipercarboxylic acids as a sterilant when dissolved in water is not obvious because the state of the knowledge of those having ordinary skill in the art was that dipercarboxylic acids that could be stored as a solid could not then be dissolved in an aqueous solution at high enough concentrations to provide a sterilant. The references cited by Applicant, and the references cited by the Examiner, support this belief.

Applicant's discovery that there are dipercarboxylic acids that may be stored as a solid and then dissolved in water at sterilant concentrations, has great utility because Applicant's invention allows sterilizing solutions to be made easily and cheaply even in areas without modern conveniences, such as on the battle field. As shown in the references cited by the Examiner and by Applicant in the Specification, use of dipercarboxylic acids in the past have had to be generated close to the site of use because of their instability. Applicant has solved this well known problem with the use of solid dipercarboxylic acids.

The last prong that must be shown by Applicant is that the claimed compound is distinctive over the existing compound. Applicant has done this in the same way as in *Wiggins, supra.* Applicant claims a solid powder having dipercarboxylic acid and exothermic control agent provided

in measured amounts to provide a sterilant having a concentration of at least 0.1 wt. % dipercarboxylic acid in an a measured amount of water, without forming an equilibrium amount of hydrogen peroxide in the sterilant, and being substantially free from organic compounds other than the one or more dipercarboxylic acids. These limitations may be considered only slight changes over the prior art compounds, but they are significant.

Applicant respectfully asserts that because an "old" compound, the bleach tablet, may produce a solution having 200 ppm dipercarboxylic acid in solution, that does not motivate or teach one having ordinary skill in the art that the dipercarboxylic acid may be used at concentrations of at least 0.1 wt. %, a much higher number. This is supported by the Court in *Wiggins*, stating "A unit dosage containing 2.5 mg [of the old composition] falls short of the 10-1000 mg amounts cited in the present claim." *Id.* at 360. Applicant claims a compound in measured amounts to form an aqueous solution having at least 0.1 wt. % dipercarboxylic acid in solution, which falls far short of the 200 ppm taught by Huber as a bleach.

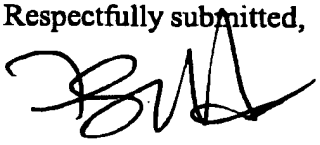
Therefore, because Applicant's claimed compound is essentially void of other organic compounds, like cellulose or starch as taught by Huber, because the product is provided in measured amounts to form a concentration of dipercarboxylic acids much greater than that required for a bleach and much higher than those having ordinary skill in the art thought possible, because the product is provided as a solid which may be used to produce a sterilant free of equilibrium amounts of hydrogen peroxide, Applicant has provided a patentable compound, even if only slight changes have been made from the prior art.

Because Applicant has shown the claimed compound to be distinctive over the existing compounds, to possess great utility and to not have been obvious, Applicant respectfully asserts that the claimed compound is patentable under the doctrine of slight changes. Reconsideration and withdrawal of the rejection is respectfully requested.

In the event there are additional charges in connection with the filing of this Response, the Commissioner is hereby authorized to charge the Deposit Account No. 50-0714/LYNN/0120.A of

the firm of the below-signed attorney in the amount of any necessary fee.

Respectfully submitted,



Frank J. Campigotto
Attorney for Applicant
Registration No. 48,130
STREETS & STEELE
13831 Northwest Freeway, Suite 355
Houston, Texas 77040
(713) 939-9444

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IN RE LESLIE FREDERICK WIGGINS

No. 7864

United States Court of Customs and Patent Appeals

55 C.C.P.A. 1356; 397 F.2d 356; 1968 CCPA LEXIS 296; 158 U.S.P.Q. (BNA) 199

Oral argument December 5, 1967

June 27, 1968 *

***** Petition for rehearing denied October 10, 1968.**

PRIOR HISTORY:
[***1]

APPEAL from Patent Office, Serial No. 125,647

DISPOSITION:
Reversed.

COUNSEL:
Janes & Aeschlimann, Christopher Aeschlimann (John R. Janes, of counsel) for appellant.

Joseph Schimmel (Raymond E. Martin, of counsel) f r the Commissioner of Patents.

OPINIONBY:

CLARK

OPINION:

[**357]

[*1357] Before WORLEY, Chief Judge, Justice CLARK, * and Judges RICH, SMITH, KIRKPATRICK. **

* Associate Justice, retired, Supreme Court f the United States, sitting by designation.

** Senior District Judge, Eastern District of Pennsylvania, sitting by designation.

CLARK, Associate Justice, delivered the opinion of the court:

This appeal is from the decision of the Board of Appeals which affirmed the examiner's rejection f claims 13-15 in appellant's application n1 as unpatentable under 35 USC 103 in view of a literature article by Wolf and Braun (Wolf). n2 After careful consideration of "the differences between the prior art and the claims at issue," Graham v. John Deere Co., 383 US 1, 17 (1966), taken as a whole and specifically in light of the teachings of Wolf, we conclude that appellant's claims comply with the conditions for patentability set forth in section 103 and reverse the [***2] decision of the board.

n1 Serial No. 125,647, filed July 21, 1961, and entitled "Pharmaceutical Preparations."

n2 Appearing in Arzneimittel Forschung, Vol. 9, pages 442-3 (July 1959) and abstracted in Chemical Abstracts, Vol. 53, page 2057e (1959)

The Application and Claims

The subject matter of the application relates to the discovery that particular chemical compounds - 1:3 benzoxazine-2:4-dione and its alkali metal salts - exhibit analgesic activity, and alleviate headache pain in humans.According t the specification, a given

compound may be administered by placing it in "any of the customary pharmaceutical forms" such as tablets, capsules, powders, pills, [*1358] ampouled soluti ns f r parenteral administration, suspensions for oral administration and the like. The amounts of the compound which may be administered are governed by its activity and toxicity, the specification stating:

The toxicity of the compound is such that doses of up to 100 milligrams may be administered orally say three times a day, whereas its activity is such that doses as low as 10 milligrams each may be employed.

Claims 13-15 read:

13. A pharmaceutical preparation in dosage unit [***3] form adapted for administration to obtain an analgesic effect, comprising, per dosage unit, an analgesically-effective non-toxic amount within the range from about 10 to about 1000 milligrams of at least one compound selected from the group consisting of 1:3-benzoxazine-2:4-dione and pharmacologically acceptable alkali metal salts thereof, and a pharmaceutical diluent.

14. A pharmaceutical preparation in accordance with claim 13 in a form adapted for oral administration.

15. A pharmaceutical preparation in accordance with claim 14 in the form of a tablet.

Certain other claims, directed to a method of obtaining an analgesic effect by administering the compounds recited in claim 13, were allowed by the examiner.

The Prior Art

The Wolf article relied on by the board discloses that, prior to appellant's discovery, the identical compound employed by appellant, 1:3-benzoxazine-2:4-dione (termed "O(2)" by Wolf) was known to protect mice against the effects of X-ray radiation. Wolf describes the method by which he ascertained such activity:

The investigations were carried out on mice weighing 16-18 g. who were submitted to radiation in groups of 20 * * *. *** The protective [***4] substance was injected in the animals by means of an i.p. [intraperitoneal] administration 10 minutes before the radiation. The dose employed was 150 mg/kg [of mouse weight]. Trials in order to demonstrate a protection after an oral administration were unsuccessful. *** [**358]

It appears Wolf also investigated other properties or activities of "O(2)," reporting that:

In contrast to Nembutal "O(2)" has no central depressant r anaesthetic pr perties. In other respects, also, the substance is pharmacologically inert. ***

That, in pertinent part, is the scope and c ntent f the pri r art reflected in the rec rd before us which, in the board's view, renders the compositi ns of the claims obvious and frames the issue before us. Subsumed is a determination of the correctness of the board's findings that none of the claim limitations relating to analgesic use, the diluent, dosage unit form, the tablet form and the dosage range are of any patentable significance.

[*1359] Difference in Subject Matter

Appellant posits four main differences between the subject matter of his claims and the disclosure of Wolf, some of which differences are rather tenous, others [***5] more substantial. Summarized they are:

(1) The claims require the presence of a "pharmaceutical diluent" as part of the compositions, whereas Wolf does not explicitly mention the use of such a diluent or carrier in administering "O(2)" to mice.

(2) The claims state that the composition is in a "dosage unit" form, a form "adapted for oral administration" and the form of a "tablet," respectively, whereas Wolf, it is said, discloses no particular form in which "O(2)" was administered to mice intraperitoneally.

(3) The claims recite the intended use of the claimed composition, viz. "to obtain an analgesic effect," whereas Wolf, dealing as he does only with agents protective against X-rays, does not remotely suggest such a use for his disclosed compositions. Indeed, appellant's composition is a "quick acting analgesic when given by the oral route" while Wolf found "O(2)" had "no central depressant or anaesthetic properties ... the substance is pharmacologically inert" and "oral administration was unsuccessful."

(4) The claims require a particular amount of active ingredient per dosage unit, viz. "an analgesically-effective non-toxic amount within the range from about 10 to 1000 [***6] milligrams" of the dione or its salts, whereas Wolf neither employs nor suggests the use of such amounts.

With respect to the first differece posed by appellant, the examiner thought that, in view of Wolf's disclosure that "O(2)" possesses what the examiner regarded as "pharmaceutical activity," it "would be obvious to include this active pharmaceutical agent with any pharmaceutical diluent," citing In re Rosicky, 47 CCPA 859, 276 F.2d 656, 125 USPQ 341 (1960). The board went one step further, stating that "The combination of the compound and a diluent or vehicle we consider is shown by Wolf." In view of appellant's apparent agreement n3 with the board on the matter, it needs no further discussi n.

n3 Appellant candidly states:

55 C.C.P.A. 1356, *; 397 F.2d 356, **;
1968 CCPA LEXIS 296, ***; 158 U.S.P.Q. (BNA) 199

> The compound is a solid, and it can be presumed (the Patent Office Board f Appeals did) that one skilled in the art would prefer to administer the compound to mice in a carrier or vehicle, since this is a conventional type of composition for intraperitoneal administration.

The remaining three differences between the claims and the prior art are best discussed together. Appellant argues that no composition containing 10-1000 milligrams of "O(2)" [***7] per dosage unit for use as an analgesic is disclosed or made obvious by Wolf. As an abstract proposition, that argument is undoubtedly true, for it seems most unlikely that one of ordinary skill in the art would consider preparation of a pharmaceutical composition containing the amounts of "O(2)" recited in the claims to be obvious for the purpose appellant sets forth, particularly in view of Wolf's statement that "O(2) has no central depressant or anaesthetic properties" and [**359] is "pharmacologically inert" in other respects also.

[*1360] [1] Nevertheless, any agreement by us with that contention is not necessarily dispositive of the issue. More to the point is whether Wolf suggests or makes obvious a composition containing, in addition to a suitable vehicle, 10 to 1000 milligrams of "O(2)" per unit dosage for the particular purpose of radiation protection. Were Wolf to describe or render obvious such a composition containing those amounts of "O(2)," that composition, of course, would not appear to differ in any material manner from the composition of appellant's claims, no matter to what ultimate use it would be put. n4

> n4 In such eventuality, appellant's discovery of the analgesic properties of "O(2)" and of a composition containing it could properly be claimed only as a method or process of using that compound or composition in accordance with the provisions of 35 USC 100(b) and 101. See In re Hack, 44 CCPA 954, 245 F.2d 246, 114 USPQ 161 (1957); In re Thuau, 30 CCPA 979, 135 F.2d 344, 57 USPQ 324 (1943), and cases cited therein. As this court stated in In re Lemin, 51 CCPA 942, 326 F.2d 437, 140 USPQ 273 (1964):
>
> Appellants are clearly correct in demanding that the subject matter as a whole must be considered under 35 U.S.C. 103. But in applying the statutory test, the differences over the prior art must be more substantial than a statement of the intended use of an old composition. Counsel for appellants produced a bottle containing a composition at oral argument. It seems to us that the composition in the bottle would be exactly the same whether the user were told to cure pneumonia in animals with it (as in Rothmann) or t promote plant growth with it (as here). The directi ns on the label will not change the composition of the contents. We therefore fail to find any unobvious distinction in the claim phrase "suitable for promoting growth of plants and for protecting them from damage by parasitic pathogens."
>
> The claim limitation "a parasitic plant pathogen inhibiting and plant growth promoting amount" could be a valid distinction, assuming the art knows what range of amounts is intended by the phrase, only if it differed from the amount that those having knowledge of the prior art here would employ for the prior art purpose. Here there is no indication that the plant protecting amount is any different from a therapeutic amount that one skilled in the art of Rothmann would select. It, therefore, does not appear that the amount limitation distinguishes the composition from that which would be obvious from the prior art. (Emphasis supplied) [***8]

Here, however, the claimed composition - certain amounts of "O(2)" plus a diluent - does appear to be new. We say that notwithstanding repeated references by the board as well as the solicitor's brief to appellant's attempt to patent the "old composition" shown by Wolf, n5 [*1361] for there seems to be no explicit description by Wolf of the amounts of "O(2)" employed by appellant in his composition. In that regard, Wolf discloses [**360] that he employed "O(2)" in amounts of 150 milligrams/kilogram of mouse weight for purposes of radiation protection. Since each mouse is said to weigh 16-18 grams, simple calculation establishes that about 2.5 milligrams of "O(2)", presumably in some suitable vehicle or carrier, was administered either intraperitoneally or orally to each mouse. A unit dosage containing 2.5 mg "O(2)" falls short of the 10-1000 mg amounts recited in the present claims.

> n5 The board stated, somewhat ambiguously we think:
>
> . In substance, claims 13, 14, and 15 merely call for an old compound in an old vehicle or diluent. We see no patentable significance in the proposed use to which the product will be put as an analgesic. The combination of the compound and a diluent or vehicle we consider is shown by Wolf et al. The intended new use does not make this old composition new and patentable. In re Thau, 30 CCPA 979; *** 135 F.2d 344; 57 USPQ 324.
>
> *** Appellant has discovered a new use f r an old composition and suitable claims to the method of using it, claims 10, 11 and 12, have

been all wed in accordance with 35 U.S.C. 101. The word "process" is defined in 35 U.S.C. 100(b) as including a new use of a known composition of matter. However, we do not consider that this known composition of matter can become new and patentable by including therewith a statement of intended use or a conventional diluent or by putting it up in dosage unit form as recited in the claims. (Emphasis supplied).

[2] We gather that the board must have meant that a combination of "O(2)" and diluent per se was not new. Were the claimed composition in fact described by Wolf in its entirety, there would seem to have been little need for a rejection under § 103. Reliance upon that statutory provision necessarily implies, by its own terms, that the subject matter "is not identically disclosed or described" by Wolf. [***9]

We find nothing in Wolf which suggests that he or any other person of ordinary skill in the art would regard the preparation or administration to mice or humans of compositions containing sufficiently greater amounts of "O(2)" as to fall within the scope of the appealed claims to be obvious. Nor apparently did the examiner and board - at least their opinions reflect no such finding. n6

n6 [3] Neither the examiner nor board found, for example, that one of ordinary skill in the art, in carrying out the teachings of Wolf, would as a matter of course prepare a composition containing larger amounts of "O(2)" in a carrier or vehicle, then divide it into aliquot portions containing 2.5 milligrams "O(2)" for administration to each of the 20 or 60 mice in each group tested. Nor did they determine whether such a stock composition would necessarily correspond in any manner to those claimed here. Under the circumstances, we think it inappropriate that we speculate on what one of ordinary skill might or might not do. In re Cofer, 53 CCPA 830, 354 F.2d 664, 148 USPQ 268, (1966).

[4] In summary, then, Wolf found that "O(2)" was not a "depressant" or "anaesthetic"; that it was otherwise [***10] "pharmacologically inert"; and that it was unsuccessful on oral application. When considered with Wolf's apparent failure to suggest appellant's claimed dosage amounts, such a triad of basic negative findings, rather than making appellant's discovery obvious, seems to us to have the direct opposite effect. Indeed, it would have had the general effect of deterring further experimentation. In United States v. Adams, 383 U.S. 39 (1966), a somewhat similar situation existed in the prior art. There the prior art suggested Adams' combination "was both dangerous and inoperable." Id. at 50. Despite that, and other prior art teachings that open circuit batteries which heated in normal use were not pratcial, and that wet batteries "were successful only when combined with electrolytes detrimental to the use of magnesium," Adams' battery - using the condemned elements - was successful, much to the surprise of the experts. The Court commented:

These long-accepted factors, when taken together, would, we believe, deter any investigation into such a combination as is used by Adams. This is not to say that one who merely discovers new uses to old inventions by shutting his eyes to their prior [***11] disadvantages thereby discovers a patentable innovation. We do say, however, that known disadvantages in old devices which would naturally discourage the search for new inventions may be taken into account in determining obviousness. At 52.

[*1362] Section 103 of the 1952 Patent Act provides that a patent may not be obtained "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." In light of the background of the subject matter here, the content of the prior art and the differences between it and appellant's claims, we cannot say that the discovery of appellant was obvious to one skilled in the art. It was certainly not obvious to Wolf and Braun and no other references are before us. Rather than "an old compound in an old vehicle" as characterized by the board, we find that, while appellant's claimed compositions [***12] are based on an old compound, it is obviously a new vehicle on a new thoroughfare.

The decision is reversed.